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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA and NEW YORK STATE *ex rel.* J. DOES, Plaintiffs, - against - EAST COAST ORTHOTIC AND PROSTHETIC CORPORATION, VINCENT A. BENENATI, AND HEALTHCARE PROVIDER DOES 1 - 30, Defendants.	**COMPLAINT** **FILED *IN CAMERA* AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)**

Plaintiffs the United States of America and the State of New York *ex rel.* J. Does ("Relators"), by and through Relators' attorneys, Sadowski Katz LLP, allege for their complaint as follows:

PRELIMINARY STATEMENT AND NATURE OF THE ACTION

This is a civil action brought by relators J. Does on their own behalf and on behalf of the United States of America ("United States") and the State of New York against East Coast Orthotic and Prosthetic Corporation ("East Coast"), Vincent A. Benenati ("Benenati,") and Healthcare Provider Does 1 – 30 ("HCPs 1-30") (collectively, East Coast and HCPs 1-30 are referred to herein as "Defendants") under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (the "False Claims Act"), and the New York False Claims Act, New York State Finance Law §§ 187

et seq., (the "New York False Claims Act"), to recover damages sustained by, and penalties owed to, the United States and the State of New York as the result of Defendants having knowingly presented or caused to be presented to the United States and the State of New York false claims for the payment of funds disbursed under the Medicare Program, 42 U.S.C. §§ 1395c-1395i-4, and Medicaid Program, 42 U.S.C. §§ 1396 *et seq.*, in excess of the amounts to which Defendants were lawfully entitled, from on or about 2009 through the present, as more specifically detailed *infra*.

1. These claims are based on Defendants' submission of false and fraudulent patient claims to the United States and the State of New York in order to obtain millions of dollars in payments for various healthcare services from 2009 through the present.

2. East Coast participated in an illegal kickback scheme and financial arrangements with HCPs 1-30 to obtain lucrative Medicare and Medicaid referrals. East Coast, in accord with established company practice, engaged in such financial relationships with physicians, practice groups, hospitals and others in return for patient referrals in violation of the Stark Statute, 42 U.S.C. § 1395nn, its implementing regulations, 42 C.F.R. § 411.350 *et seq.* (collectively, the "Stark Laws") and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and then submitted or caused to be submitted false and fraudulent claims and statements to the United States and the State of New York, and received payments for services rendered to patients referred by those physicians, practice groups, hospitals and other health care providers.

3. East Coast offered remuneration to referring physicians by entering into illegal exclusive contractual joint venture services agreements, whereby it induced physicians, practice groups, and HCPs 1-30 to refer to it numerous Medicare and Medicaid patients. Physicians, practice groups, HCPs 1-30, and East Coast in turn, billed Medicare, Medicaid, and other

government healthcare programs for those services. Pursuant to the illegal joint venture, East Coast provided physicians, practice groups, and HCPs 1-30 with orthotists, prosthetists, inventory, and inventory management directly on site in the physician's offices, at no cost to the physicians. The physicians could then bill Medicare and Medicaid for these products and services, dramatically increasing physician profit. In some instances, East Coast billed Medicare and Medicaid directly. Defendants directly and indirectly caused physicians, practice groups and HCPs 1-30 to submit false claims to and obtained millions of dollars in payments from the United States and the State of New York, which were each tainted by the violation of the Anti-Kickback Statute and the Stark Laws, and therefore each violated the False Claims Act.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the claims brought under the False Claims Act and the New York False Claims Act pursuant to 31 U.S.C. § 3730(b)(1), 28 U.S.C. §§ 1331, 1345, and 1367.

5. Venue lies in this District pursuant to 31 U.S.C. §§ 3732(a) and (b), and 28 U.S.C. §§ 1391(b) and 1391(c), because Defendants are headquartered and located in this District, do business in this District, and because many of the acts complained of herein took place in this District.

PARTIES

6. Plaintiffs are the United States of America on behalf of its agency the United States Department of Health and Human Services ("HHS") and the State of New York on behalf of its agency the Department of Health ("DOH").

7. Relators J. Does reside in New York State. Each Relator has personal knowledge of the facts and is an original source, which they have voluntarily provided to the Government.

8. East Coast is a corporation organized under the laws of New York, with its principal office at 75 Burt Drive, Deer Park, New York 11729, that provides orthotics, prosthetics, and orthotic-related services.

9. Vincent A. Benenati is the Chief Executive officer of East Coast.

10. HCPs 1-30 are physicians, practice groups, hospitals and other health care providers that entered into illegal exclusive contracts with East Coast to provide orthotics and orthotics-related services.

THE LAW

A. The Medicare Program

11. The United States, through HHS, administers the Medicare Program for the aged and disabled and was established by Title XVIII of the Social Security Act. 42 U.S.C. §§ 1395 *et seq.* Part A of the Medicare Program provides federal payment for patient institutional care, including hospitals, skilled nursing facility, and home healthcare. 42 U.S.C. §§ 1395c-1395i-4. Part B of the Medicare Program provides supplemental insurance coverage for medical and other services that are not covered by Part A. 42 U.S.C. §§ 1395j-1395w-4.

12. The Centers for Medicare and Medicaid Services ("CMS") is the governmental body responsible for the administration of the Medicare Program.

13. Under the Medicare Program, CMS makes payments to medical providers, such as physicians and orthotic and prosthetic providers, for inpatient and outpatient services after the services are rendered. Medicare enters into provider agreements with hospitals, physicians, and other medical providers that govern their participation in the program. Under Medicare, reimbursement is prohibited if the item or service is not "reasonable and necessary for the diagnosis and treatment of illness or injury . . . ." 42 U.S.C. § 1395y(a)(1)(A).

14. Outpatient services, such as outpatient medical equipment like orthotic and prosthetics and related services, are paid based on a fee schedule in accordance with Section 1833(h) of the Social Security Act.

15. In order to be reimbursed by Medicare, a provider must enroll in the Medicare program and submit an enrollment application to CMS. Every such enrollment application contains a "Certification Statement" that must be signed by an appointed official of the provider, such as its chief executive officer. The appointed official is required to certify, in pertinent part, that:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

CMS Form 855B.

16. Upon information and belief, at all times relevant hereto, HCPs 1-30 were required to and did submit a Medicare enrollment application to CMS.

17. Upon information and belief, at all times relevant hereto, appointed officials of HCPs 1-30 signed the Certification Statement contained in such enrollment applications.

B. The Medicaid Program

18. The Medicaid program was created by Title XIX of the Social Security Act to provide healthcare benefits for poor and disabled individuals. 42 U.S.C. §§ 1396-1396v. The Medicaid program is funded by both state and federal funds, with the federal contribution computed separately for each state. 42 U.S.C. §§ 1396b, 1396d(b). Medicaid is administered at the federal level by CMS. Federal involvement in Medicaid is largely limited to providing

matching funds and ensuring that the states comply with minimum standards in the administration of the program.

19. The federal Medicaid statute sets forth the minimum requirements for state Medicaid Programs to qualify for federal funding, which is called federal financial participation ("FFP"). 42 U.S.C. §§ 1396 *et seq.*

20. Upon information and belief, HCPs 1 - 30 sought reimbursement from the Medicaid Program for the time period pertinent to this Complaint.

C. The Federal False Claims Act

21. The False Claims Act provides, in pertinent part, that:

> any person who –
> (A) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);
> * * *
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,
>
> is liable to the United States Government for a civil penalty of not less than $5,500 and not more than $11,000… plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729; 64 Fed. Reg. 47,099 (1999).

22. False certifications constitute false claims under the False Claims Act.

D. The New York False Claims Act

23. The New York False Claims Act provides in pertinent part that:

> any person who:
> (a) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;

> (b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> (c) conspires to commit a violation of paragraph (a), (b), (d), (e), (f) or (g) of this subdivision;
> * * *
> (g) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state or a local government;
> (h) . . . shall be liable to the state or a local government, as applicable, for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of all damages, including consequential damages, which the state or local government sustains because of the act of that person.

New York State Finance Law §§ 189 (1)(a), (b), (c), (g), (h).

E. The Anti-Kickback Statute

24. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that payoffs to those who can influence healthcare decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of the program from these difficult to detect harms, Congress enacted a *per se* prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gave rise to overutilization or poor quality of care. First enacted in 1972, Congress strengthened the statute in 1977 and again in 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b; Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

25. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending, or arranging for

federally-funded medical services, including services provided under the Medicare, Medicaid and TRICARE programs. 42 U.S.C. § 1320a-7b(b).

26. The Anti-Kickback Statute criminalizes such actions as:

> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--
>
> > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> > (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b)(2)(A)-(B).

27. The term "any remuneration" encompasses any kickback, bribe, or rebate, direct or indirect, overt or covert, in cash or in kind. 42 U.S.C. § 1320a-7b(b)(1).

F. The Stark Laws

28. Enacted as amendments to the Social Security Act, 42 U.S.C. § 1395nn (commonly known as the "Stark Statute"), the Stark Statute prohibits a health care provider, such as an orthotic supplier, from submitting Medicare and Medicaid claims for payment based on patient referrals from physicians having a "financial relationship" (as defined in the statute) with the health care provider. The regulations implementing 42 U.S.C. § 1395nn expressly require that any provider collecting payment for a healthcare service "performed under a prohibited referral must refund all collected amounts on a timely basis." 42 C.F.R. § 411.353.

29. The Stark Laws (defined below) established the clear rule that the government will not pay for items or services prescribed by physicians who have improper financial

relationships with other providers. In enacting the statute, Congress found that financial relationships between physicians and entities to whom they refer patients can compromise physicians' professional judgment as to whether an item or service is medically necessary, safe, effective, and of good quality. Congress relied upon various academic studies consistently showing that physicians who had financial relationships health care providers ordered more of those providers' services than physicians without those financial relationships. The Stark Laws (defined below) were designed specifically to reduce the loss suffered by the Medicare and Medicaid programs due to such questionable overutilization of services.

30. In 1993, Congress extended the Stark Statute ("Stark II" or "Stark Laws") to referrals for ten additional designated health services ("DHS"). Stark II also extended aspects of the Medicare prohibition on physician referrals to Medicaid. *See* Omnibus Reconciliation Act of 1993, P.L. 103-66, §§ 13562, 13624; Social Security Act Amendments of 1994, P.L. 103-432, § 152. Section 13624 of the Omnibus Budget Reconciliation Act of 1993 extended aspects of the Medicare prohibition on physician referrals to Medicaid.

31. In pertinent part, the Stark Statute provides:

> (a) Prohibition of certain referrals
> (1) In general
> Except as provided in subsection (b) of this section, if a physician (or immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2) then—
>
> (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter,
>
> (B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third-party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

42 U.S.C. § 1395nn (emphasis added).

32. The Stark Laws broadly define prohibited financial relationships to include any compensation paid directly or indirectly to a referring physician, subject to certain exceptions not applicable in this case. 42 C.F.R. § 411.354. The financial relationships that trigger the prohibition on referrals include any ownership or investment interest in the entity as well as any compensation arrangement with the entity, unless an exception applies. *Id.* Indirect financial arrangements in which the relationship is formed through an intervening third party are also included. *Id.* at 411.354(a)(2)(ii).

33. A *direct* financial relationship exists if remuneration passes between the referring physician and the entity furnishing DHS. *Id.* at 411.354(a)(2)(i). Remuneration means any payment or other benefits made directly or indirectly, overtly or covertly, in cash or in kind. 42 C.F.R. § 351. Remuneration includes the leasing of equipment and the provision of services and benefits.

34. A "referral" means a request by a physician for an item or service for which a payment may be made under Medicare, including a request for a consultation (including any tests or procedures ordered or performed by the consulting physician or under the supervision of the consulting physician), and the request or establishment of a plan of care by a physician that includes the furnishing of DHS (with certain exceptions for consultations by pathologists, diagnostic radiologists, and radiation oncologists). 42 U.S.C. § 1395nn(h)(5).

35. The Stark Laws prohibit the billing of DHS provided as a result of a prohibited referral. 42 C.F.R. § 411.353(b). An entity that receives a prohibited referral may not present a claim, or cause the presentation of such claim to Medicare or Medicaid or other third-party payer for reimbursement of the services. *Id.*

36. An entity that collects payment for DHS that was performed under a prohibited referral must refund all collected amounts on a timely basis. *Id.* at 411.353(d).

37. In sum, the Stark Laws prohibit health care providers from billing Medicare for certain designated services referred by a physician with whom the provider has a financial relationship of any type not falling within specific statutory exceptions. 42 U.S.C. § 1395nn.

G. Contractual Joint Ventures

38. Contractual joint ventures between physician referrers of business and providers such as those providing durable medical equipment are inherently suspect as violations of the Anti-Kickback Statute and the Stark Laws.

39. In 2003, and again in 2006, the Office of the Inspector General issued bulletins and advisory opinions that list the characteristic of prohibited arrangements. Special Advisory Bulletin, Contractual Joint Ventures, Department of Health and Human Services, Office of Inspector General, April 2003, at http://oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVentures.pdf ("2003 Bulletin"); OIG Advisory Opinion No. 06-02, Department of Health and Human Services, Office of Inspector General, March 21, 2006, at https://oig.hhs.gov/fraud/docs/advisoryopinions/2006/ao0602.pdf ("2006 Advisory Opinion").

40. The first characteristic of a prohibited "joint venture" is when the provider seeks to expand into a line of ancillary services that can be provided to the provider's existing patients. *See* 2003 Bulletin.

41. The second characteristic of a prohibited "joint venture" is when the new line of business predominantly or exclusively services the owner's existing patient base, and the provider does not intend to expand the provider's business to service other patients. *Id.*

42. The third characteristic of this prohibited venture is the limited business risk for the provider. The provider's primary, perhaps sole, contribution to the new business is referrals. There is no *bona fide* business risk to the provider. *Id.*

43. The fourth characteristic of this prohibited venture is that the supplier is a potential competitor. *Id.*

44. The fifth characteristic of this prohibited venture is the broad scope of the services provided to the referring physician, with the physician's major contribution being referrals. *Id.*

45. The sixth characteristic of this prohibited venture is where remuneration is tied to volume and value. *Id.*

46. Finally, the seventh characteristic of this prohibited venture is its exclusivity. *Id.*

THE FACTS

THE IMPROPER FINANCIAL RELATIONSHIP AND KICKBACK SCHEME

47. During the relevant time period, East Coast was aware of the prohibitions and restrictions on its financial relationships with referring physicians. This information was known to the East Coast's officers, including, but not limited to its Chief Executive Officer, Vincent A. Benenati. Despite this knowledge, East Coast initiated a plan to target certain physicians and physician practice groups and enter into unlawful financial relationships to induce physicians to make patient referrals to East Coast, including referrals of Medicare and Medicaid patients. East Coast either itself or knowingly caused those physicians, HCPs 1-30, to bill for and collect millions of dollars in reimbursement from the United States and New York State based on the services East Coast provided for those referred patients.

48. As described by Benenati himself in a solicitation to the Brooklyn Spine and Arthritis Center:

> About five years ago [2009], we started working with practices with an optional business model where we provide the same services to the practice but the practice (physician) bills for the services and we are a subcontractor. Most insurance carriers reimburse physicians more than we as a company get reimbursed, so this has become a win-win situation for both parties involved.
>
> How profitable is it for a physician? On average, a single physician can see monthly profits of $10,000 after expenses. Of course, this is based on how busy and what their insurance mix is. We provide a multitude of services in this model; we provide the inventory (at no cost to the practice), the Orthotist or Orthotic Fitter (who would work in your practice full time, once again, at no charge to the facility) and we would handle all the authorizations for the products that we provide at your location. We have an implementation team that will work with your billing department and monthly go over denials and any billing issues or concerns. On patients that your practice can not [sic] bill, East Coast Orthotic & Prosthetic Corp. will bill those carriers directly.

49. In Benenati's January 21, 2014 solicitation, he touted: "Some notable practices that have successful implemented with [sic] this model include SUNY Buffalo, Columbia Orthopedics, practices at NYU, Hospital for Special Surgery and Westchester Medical Center. We have over 150 orthopedic surgeons involved, with new practices joining us monthly."

50. Benenati claimed that East Coast "has been on-site at SUNY Downstate for the last 14 years and we also used to come [to] . . . Methodist [Hospital in Brooklyn], working with Dr. Michael Vitale a number of years ago."

51. East Coast's arrangement was memorialized in an "Orthotic and Prosthetic Services Agreement" (the "Agreement"). Under the Agreement, East Coast was the "Contractor" and the physician or practice was denoted as the "Provider."

52. Under the Agreement, the Contractor agreed to perform the following services for the Provider:

- Supply services and orthotic and prosthetic devices ("Product") in accordance with a Price List attached to the Agreement;
- Order, fit and finish custom Products in accordance with the Price List;

- Deliver charge sheets to Provider's biller;
- Obtain authorization from patient's insurance carriers for prescribed Product; and
- Provide orthotists, orthotic fitters, and/or prosthetists to apply braces and prosthetics, perform casting/measuring for custom devices, train patients on Product usage; and supply patients with wear and care information.

53. The prices reflected in the Price List "are all-inclusive prices and incorporate charges for all of the Services" supplied by the Contractor.

54. The Agreement provides that the orthotists, orthotic fitters, and prosthetists will be available at **all** of the Provider's locations during normal business hours, and on call outside of normal business hours, including weekends.

55. The Agreement provides that the Contractor "shall be the exclusive contractor providing Services in **all** of Provider's locations."

56. According to the Agreement, the Provider is responsible for "all management and administrative services in connection with the provision of the Products and Services to . . . patients . . . including billing, secretarial, and scheduling."

57. Under the Agreement, the "Contractor will maintain in the supply room or locker in the premises of the Provider premises . . . an inventory of Products . . . for the use by Provider."

58. The Agreement states that "Provider shall be entitled to bill patients and their insurance carriers (and other third-party payors) and collect fees for all Services and all Products provided to its patients . . ."

59. The Price List attached to the Agreement lists the Products by HCPS code, description, Medicare allowable reimbursement and the charge East Coast bills the Provider for each Product. According to the Price List, East Coast charges the contracting Provider 45% of the Medicare allowable reimbursement on each Product East Coast provides.

60. Under the Agreement, East Coast provides incredible value to Providers on site at the physician's own office: (1) Personal services to order, fit, cast, take measurements, to obtain prior authorizations, to train patients, to supply wear and care information, and to assist the physician in billing and collections (:Services"); and (2) Product.

61. Moreover, for each Product provided to the Provider, Contractor bills the Provider 45% of the Medicare allowable reimbursement for that Product, without taking into account any of the Services provided to the Provider *(i.e.*, fitting the orthotics, assisting in billing and collections), or the actual price to East Coast of the Product.

62. The Agreement states that the "Contractor's fees for the Products and Services provided under this Agreement are the fair market value thereof, negotiated at arms-length, and are not inflated or reduced to take into account business generated between the parties," (Agreement ¶ 5 (d)). Given that the price charged to the physicians is always 45% of the Medicare allowable reimbursement for the Product, regardless of the amount of effort involved, the amount of Service provided, or the actual cost of the item, this statement is false.

63. Instead, each charge by East Coast to HCPs 1-30 should be the combination of two components: (1) the Services provided to the physician's office and patient; and (2) the fair market value of each specific Product provided.

64. In actuality, East Coast charges the physician nothing for the Services component. Providing services free-of-charge in the physician's own office is an incentive to the physician to obtain referrals.

65. The East Coast Agreement bears every characteristic of an illegal arrangement violating the Anti-Kickback Statute and the Stark Laws.

66. First, the second Whereas clause of the Agreement states "Provider wishes to establish a program to provide Products ancillary to Provider's orthopedic surgery practice and to be able to bill insurers and other payors for such Products . . . ." This demonstrates that the Provider seeks to expand into a line of ancillary services that can be provided to the Provider's existing patients.

67. Second, the intent of the Agreement is to capture another avenue of billing payors, without any expansion of the Provider's operation or patient base.

68. Third, in East Coast's Agreement, the Provider is not asked to take any financial risks. All of the Products needed to fit and treat the physician's patients are owned by East Coast. The business only exists by virtue of the referral of patients by the physician to East Coast.

69. Fourth, absent the Agreement, East Coast would have had to compete for the referral of services. Indeed, the Providers could potentially provide the services themselves and compete with East Coast. However, given East Coast's location at the Provider's offices, and the free provision of Services, Providers refer the business to East Coast.

70. Indeed, here, the relationship is so close that East Coast states in its letter of solicitation to the Brooklyn Spine and Arthritis Center that for patients for whom a physician practice cannot bill, East Coast will bill those patient's insurance carriers directly.

71. Fifth, the Agreement provides that East Coast will provide essentially all the services. East Coast offers what appears to be a "turnkey" operation, including day to day management, billing, equipment, personnel, supplies, and inventory. East Coast provides every essential component needed to operate a durable medical equipment company to the physician, including the inventory, prior authorizations, training of patients, casting and measuring, providing trained personnel to fit the patients, assistance with billing and collections, and East Coast will even assist the physician with government audits. All the physicians need to do is refer their patients.

72. Sixth, the practical effect of the Agreement is to provide the Providers with the ability to collect revenue for services provided by East Coast. The amount of the remuneration to the physician will vary with the value and volume of referrals generated for the venture by the physician. East Coast bills the physician on a case by case basis for the Product it provides to the physician's patients and the amount East Coast bills the physician varies from month to month based on the amount of referrals the physician gives to East Coast each month.

73. Finally, the Agreement provides that East Cost will be the exclusive Contractor in all of the physician's offices.

74. Specific Examples of Prohibited Practices:

75. On or about June 30, 2017, Mark Rodman, Regional Manager-Long Island, Queens and Brooklyn, informed the staff of East Coast who worked in the field that each Staff member who fit certain devices would receive $25.00. The devices included in this incentive pay included: knee unloader, custom knee brace, LSO (631 or 637), or bone stimulator. These are all high reimbursement devices.

76. On or about April 7, 2017, Mark Rodman wrote to the technicians who work with physicians, the following: "When given the opportunity to suggest items to the doctor[,] do you? Do we try to promote certain products over others? I was at one site one day and the doctor wanted something more than a cock-up wrist splint but didn't want to put the patient in a cast[,] I suggested the EXOS, he loved it and uses them more now (they pay much hire (sic) too). Another location gives out wrap around knee braces like crazy. Perhaps those patients if they have OA should be getting an unloader brace (another high price item)." The April 7 email also alerts the technicians of the $25,00 incentive payment for certain products.

77. East Coast has a contract with New York Methodist Hospital's RYC Orthopaedics where an East Coast employee works. On October 23, 2017, Medicare beneficiary RD was prescribed a Spanlink RAD shoulder system universal by doctor Craig Capeci. The East Coast employee assigned to New York Methodist filled out the Patient Product Agreement & Proof of Delivery and Documentation of Medical Necessity, which was then signed by Dr. Capeci. The East Coast employee performed all aspects of seeking any necessary approvals, filling out paperwork, including the prescription and fitting the equipment.

78. On October 2, 2017 Medicare beneficiary JW was prescribed a RED2XL Hinged Knee Brace with Spacer Fabric, 2XL by doctor Craig Capeci. The East Coast employee assigned to New York Methodist filled out the Patient Product Agreement & Proof of Delivery and Documentation of Medical Necessity, which was then signed by Dr. Capeci. The East Coast employee performed all aspects of seeking and necessary approvals, filling out paperwork, including the prescription and fitting the equipment.

79. East Coast has a contract with Maimonides Medical Center. On April 10, 2015, Dr. John Munyak, with an office at 6010 Bay Parkway, 6th Floor, Brooklyn NY 11204, was delivered equipment from East Coast for three patients.

80. There are two types of prohibited arrangements that East Coast uses, in one arrange a billing company affiliated with East Coast known as ECOP processes orders and performs billing for health care provides who do not have arrangements with carriers.

81. In the other arrangement known as "Wholesale," the health care provider bills the insurer, such as Medicare and Medicaid and pay East Coast a scheduled price for the prosthetic. East Coast is pushing its contracted health care providers to the Wholesale method.

82. The health care providers who currently have contracts with East Coast include the following institutions and Orthopedists have prohibited contracts with East Coat

RYC Orthopedics at 1056 5th Avenue, New York, New York 10028

Physicians: Dr. Youm, Dr. Capeci; and Dr. Husain (All Wholesale)

NY Presbyterian: Weill Cornell at 525 East 68th Street, New York, NY 10021

Physicians: Dr. Lorich, Dr. Wellman, Dr. Lane, Dr. DiFelice, Dr. Sculco, Dr. Gellhorn, Dr. Fufa (All orders are processed through ECOP)

SUNY Downstate Medical Center at 450 Clarkson Avenue, Brooklyn, NY 11203

Physicians: Dr. Barbash, Dr. Persaud, Dr. Urban, Dr. Uribe, Dr. Braun, Dr. Hesham, Dr. Paulino, Dr. Maheshwari, Dr. Casagrande. (All order processed through ECOP).

Staten Island University Hospital Depart of Pediatric Orthopedics at 2955 Veterans Rd, West Staten Island, NY 10309

Physicians: Dr. Qusai Hammouri (All Orders through ECOP).

Beth Israel Medical Center Phillips Ambulatory Care Center at 10 Union Square East 3M New York, NY 10003

Physicians: Dr. Steven Arsht, Dr. Catherine Compito, Dr. Frances Cuomo, Dr. Christopher Hubbard, Dr. Donald Kastenbaum, Dr. Peter D. McCann, Dr. Den Miyasaka, Dr. Sheldon Simon (All orders processed through ECOP).

Columbia Doctors @ Childrens Hospital of NY ("CHONY") at 3959 Broadway 8th Floor Room N833N, New York, NY 10032

Physicians: Dr. Joshua Hyman, Dr. Ben Roye, Dr. Michael Vitale, Dr. Joseph Dutkowsky, Dr. Charles Popkin, Dr. Francis Lee, Marina Gazayeva NP, Amber Sentell NP, Jen Crotty NP, Katie Fields NP (All orders are Wholesale).

Columbia Doctors/Grand Orthopedics at 500 Grand Avenue Floor 1, Suite 101, Englewood, NJ 07631

Physicians: Dr. Ahmad, Dr. Strauch, Dr. Bottiglieri, Dr. Lynch, Dr. Jobin, Dr. Popin, Dr. Hyman, Dr. Necessian, Dr. Rosenwasser, Dr. Kim, Dr. Lee, Dr. Geller, Dr. Levine, Dr. Greisberg, Dr. Vosseller (All orders are Wholesale).

Irving at 161 Fort Washington Avenue, 2nd Floor, New York, NY 10032

Physicians: Dr. Greisberg, Dr. Vosseller, Dr. Popkin, Dr. Nercessian, Dr. Strauch, Dr. Evangelista, Dr. Lynch (All orders are Wholesale).

83. Other institutions with Wholesale arrangements with East Coast include: University Orthopaedics at 19 Bradhurst Avenue, Suite 13000, Hawthorne NY 10532; Columbia

Doctors, Midtown at 51 West 51st Street, 3rd Floor Suite 370 New York, NY 10019; Erie County Medical Center; University Orthopaedics at 4949 Harlem Road, Amherst, NY 14226; UB/MD Orthopedics & Sports Medicine at 5959 Big Tree Rd., Suite 108, Orchard Park, NY 14127; Columbia Doctors @ Tarrytown at 155 White Plains Road, Suite W100, Tarrytown, NY 10591; Specialty Orthopaedics at 600 Mamaronek Avenue, Suite 101, Harrison, NY 10528; Dr. Shubin Stein at 535 East 70th Street 6th Floor, New York, NY 10021; University Orthopaedics at 200 Westage Business Center, Suite 115, Fishkill, NY 12524; Dr. Alan J. Dayan, MD PC at 1715 Avenue T, Brooklyn, NY 11229; Dr. DiFelice at 520 East 70th Street, 2nd Floor, New York, NY 10021 and at 140 Ridgewood Avenue, Paramus, NJ 07652; Maimonides Bone & Joint Center at 6010 Bay Parkway, Brooklyn, NY 11204; Dr. Dean Lorich at 520 East 70th Street, 2d Floor, New York, NY 10021; Columbia Orthopedics at 590 5th Avenue, 5th Floor, New York, NY 10036; RYC Park Ave at 1095 Park Avenue, New York, NY 10128; Upper East Orthopedics at 315 East 83rd Street, New York, NY 10028; Children's Specialty Center, Stanford Hospital: Tully Health Center, 32 Strawberry Hill Ct., 4th Fl, Suite 7, Stamford, CT 06902; Lawrence Hospital Assoc./ Columbia Doctors, 85 Pondfield Rd., Bronxville, NY 11708.

84. Institutions with ECOP arrangements with East Coast include: Millard Fillmore Surgery Center at 215 Klein Road, Buffalo, NY 14221; Jacobi Medical Center at 215 Klein Road, Buffalo, NY 14221; Bellevue Hospital Center at 462 1st Avenue (Clinic 1A, Building B), New York, NY 10016; Wert Orthopaedic Surgery & Sports Medicine at 3075 Brighton 13th Street, Brooklyn, NY 11235; White Plains Physician Associates at 22 Westchester Avenue, Suite 101, White Plains, NY 10604; New York Methodist Hospital at 263 7th Avenue, Suite 2B, Brooklyn, NY 11215; New York Hospital Queens—Department of Orthopaedics, 163-03 Horace Harding Expressway, 4th Floor, Fresh Meadows, NY 11365; New York Hospital Queens—

Department of Orthopaedics at 5645 Main Street, 4th Floor, South Wing, Flushing, NY 11355; NYU Langone Seaport Orthopedics at 233 Broadway, Suite 640, New York 10279; NYU Langone Ambulatory Care—Long Island at 1999 Marcus Avenue, Suite 306, Lake Success, NY 11042; Stonybrook University Hospital at 101 Nicholls Rd, Stonybrook, NY 11794; NYP Queens (Jackson Heights) at 72-06 Northern Blvd., 2nd Floor, Jackson Heights, NY 11372; NYPQ—Sunnyside at 47-01 Queens Blvd., Suite 403, Sunnyside, NY 11104; Millstream Office at 14 Millstream Lane, Stonybrook, NY 11790; NYPQ—Downtown Flushing, at 136-56 39th Avenue, 2nd Floor, Flushing, NY 11354.

85. By entering into the Agreement with numerous providers, East Coast and the identified providers violated the Stark Laws and the Anti-Kickback Statute. Therefore, each time the Health Providers as well as ECOP billed Medicare and Medicaid for orthotic service provided by a patient referred under the Agreement, they knowingly submitted a false claim to Medicare and Medicaid, which East Coast knowingly caused them to make.

SUMMARY AND CONCLUSION

86. East Coast and the Health Providers have demonstrated their knowing willful scheme to evade the requirements of the Stark Laws, the Anti-Kickback Statute, and other applicable rules and laws, to receive payments from Medicare, Medicaid and other federal healthcare programs that they are not entitled to, by their schemes and financial relationships its referring physicians.

FIRST CLAIM

Violations of the False Claims Act
(31 U.S.C. § 3729 (a)(1)(A))
Presenting False Claims for Payment

87. Plaintiffs incorporate by reference paragraphs 1 through 86 above as if fully set forth herein.

88. The United States seeks relief against Defendants under Section 3729(a)(1)(A) of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

89. As set forth above, Defendants certified their compliance with the Stark Laws and the Anti-Kickback Statute. Defendants, knowingly or acting with deliberate ignorance or with reckless disregard for the truth, presented, or caused to be presented, to an officer, employee or agent of the United States, false and fraudulent claims for payment or approval in connection with the submission of its requests for reimbursement under the Medicare, Medicaid and other federal healthcare programs.

90. The United States paid Defendants under the Medicare, Medicaid and other federal healthcare programs because of Defendants' fraudulent conduct.

91. By reason of the Defendants' false claims, the United States has been damaged in a substantial amount to be determined at trial.

SECOND CLAIM

Violations of the False Claims Act
(31 U.S.C. § 3729 (a)(1)(B))
Use of False Statements

92. Plaintiffs incorporate by reference paragraphs 1 through 86 above as if fully set forth herein.

93. The United States seeks relief against Defendants under Section § 3729(a)(1)(B) of the False Claims Act, 31 U.S.C. 3729(a)(1)(B).

94. As set forth above, Defendants certified their compliance with the Stark Laws and the Anti-Kickback Statute. Defendants, knowingly or acting in deliberate ignorance or in reckless disregard for the truth, made, used, or caused to be made and used, false records and statements, in order to get false or fraudulent claims paid or approved by the United States in connection with the submission of its requests for reimbursement under the Medicare, Medicaid and other Federal healthcare programs.

95. The United States paid such false or fraudulent claims because of Defendants' acts and conduct.

96. By reason of Defendants' false claims, the United States has been damaged in a substantial amount to be determined at trial.

THIRD CLAIM

Violations of the False Claims Act
(31 U.S.C. § 3729 (a)(1)(G))
Use of False Statements

97. Plaintiffs incorporate by reference paragraphs 1 through 86 above as if fully set forth herein.

98. The United States seeks relief against Defendants under Section § 3729(a)(1)(G) of the False Claims Act, 31 U.S.C. § 3729(a)(1)(G).

99. As set forth above, Defendants certified their compliance with the Stark Laws and the Anti-Kickback Statute. Defendants, knowingly or acting in deliberate ignorance or in reckless disregard for the truth, made, used, and caused to be made and used, false records and statements, in order to conceal, avoid, or decrease the obligation to pay or transmit money or property to the United States in connection with the submission of its requests for reimbursement under the Medicare, Medicaid and other federal healthcare programs.

100. Defendants failed to pay or transmit money due to the United States because Defendants' acts and conduct.

101. By reason of the Defendants' use of false statements, the United States has been damaged in a substantial amount to be determined at trial.

FOURTH CLAIM

Violations of the False Claims Act
(31 U.S.C. § 3729(a)(1)(C))
Conspiracy to Commit Violations of the False Claims Act
(Against All Defendants)

102. Plaintiffs incorporate by reference paragraphs 1 through 86 above as if fully set forth herein.

103. The United States seeks relief against Defendants under Section 3729(a)(1)(C) of the False Claims Act, 31 U.S.C. § 3729(a)(1)(C).

104. As set forth above, Defendants conspired to commit a violation of subparagraph (A), (B), and (G) of the False Claims Act. Defendants have committed at least one overt act in furtherance of their conspiracy.

105. By reason of the Defendants' conspiracy, the United States has been damaged in a substantial amount to be determined at trial.

FIFTH CLAIM

Violation of the New York False Claims Act
(NY State Finance Law § 189 (1)(a))
Presenting False Claims for Payment

106. Plaintiffs incorporate by reference paragraphs 1 through 86 above as if fully set forth herein.

107. The State of New York seeks relief against Defendants under Section 189 (1)(a) of the New York False Claims Act, NY State Finance Law § 189 (1)(a).

108. As set forth above, Defendants certified their compliance with the Stark Laws and the Anti-Kickback Statute. Defendants, knowingly or acting with deliberate ignorance or with reckless disregard for the truth, presented, or caused to be presented, to an officer, employee or agent of the State of New York, false and fraudulent claims for payment or approval in connection with the submission of Defendants' requests for reimbursement under the Medicaid and other New York state healthcare programs in violation of the Stark Laws and Anti-Kickback Statute.

109. The State of New York paid Defendants under the Medicaid and other New York state healthcare programs because of Defendants' fraudulent conduct.

110. By reason of Defendants' conduct, the State of New York has been damaged in a substantial amount to be determined at trial.

SIXTH CLAIM

Violation of the New York False Claims Act
(NY State Finance Law § 189 (1)(b))
Use of False Statements

111. Plaintiffs incorporate by reference paragraphs 1 through 86 above as if fully set forth herein.

112. The State of New York seeks relief against Defendants under Section 189 (1)(b) of the New York False Claims Act, NY State Finance Law § 189 (1)(b).

113. As set forth above, the Defendants certified their compliance with the Stark Laws and the Anti-Kickback Statute. Defendants, knowingly or acting in deliberate ignorance or in reckless disregard for the truth, made, used, or caused to be made and used, false records and statements, in order to get false or fraudulent claims paid or approved by the State of New York in connection with the submission of Defendants' requests for reimbursement under the

Medicaid and other New York state healthcare programs in violation of the Stark Laws and the Anti-Kickback Statute.

114. The State of New York paid Defendants under the Medicaid and other New York state healthcare programs because of Defendants' fraudulent conduct.

115. By reason of Defendants' conduct, the State of New York has been damaged in a substantial amount to be determined at trial.

SEVENTH CLAIM

Violation of the New York False Claims Act
(NY State Finance Law § 189 (1)(g))
Use of False Statements

116. Plaintiffs incorporate by reference paragraphs 1 through 86 above as if fully set forth herein.

117. The State of New York seeks relief against Defendants under Section 189 (1)(g) of the New York False Claims Act, NY State Finance Law § 189 (1)(g).

118. As set forth above, the Defendants certified their compliance with the Stark Laws and the Anti-Kickback Statute. Defendants, knowingly or acting in deliberate ignorance or in reckless disregard for the truth, made, used, and caused to be made and used, false records and statements, in order to conceal, avoid, or decrease the obligation to pay or transmit money or property to the State of New York in connection with the submission of Defendants' requests for reimbursement under the Medicaid and other New York state healthcare programs in violation of the Stark Laws and the Anti-Kickback Statute.

119. Defendants failed to pay or transmit money due to the State of New York because of Defendants' acts and conduct.

120. By reason of Defendants' acts and conduct, the State of New York has been damaged in a substantial amount to be determined at trial.

EIGHTH CLAIM

Violation of the New York False Claims Act
(NY State Finance Law § 189 (1)(c))

121. Plaintiffs incorporate by reference paragraphs 1 through 86 above as if fully set forth herein.

122. The State of New York seeks relief against Defendants under Section 189 (1)(c) of the New York False Claims Act, NY State Finance Law § 189 (1)(c).

123. As set forth above, Defendants conspired to commit a violation of subparagraphs (1)(a)), (1)(b), and (1)(g) of the New York False Claims Act. Defendants have committed at least one overt act in furtherance of their conspiracy.

124. By reason of the Defendants' conspiracy, State of New York has been damaged in a substantial amount to be determined at trial.

WHEREFORE, plaintiffs the United States and the State of New York *ex rel.* J. Doe, request that judgment be entered in their favor and against Defendants as follows:

(a) On the First, Second, Third, and Fourth Claims for relief (Violations of the False Claims Act, 31 U.S.C. § 3729(a) (1) (A), (B), (C) and (G), for treble the United States' damages, in an amount to be determined at trial, plus an $11,000 penalty for each false claim; and

(b) Awarding J. Does their relators' share pursuant to 31 U.S.C. § 3730(d)(1) or (2); and

(c) On the First, Second, Third, and Fourth Claims for Relief, an award of costs and attorney's fees pursuant to 31 U.S.C. § 3730(d); and

(d) On the Fifth and Sixth, Seventh, and Eighth Claims for relief (Violations of the New York False Claims Act, NY State Finance Law § 189 (1) (a), (b), (c), and (g), for treble the State of New York's damages, in an amount to be determined at trial, plus a $12,000 penalty for each false claim; and

(e) Awarding J. Does their relators' share pursuant to NY State Finance Law § 190(6); and

(f) On the Fifth, Sixth, Seventh, and Eighth Claims for Relief, an award of costs and attorney's fees pursuant to NY State Finance Law § 190(7); and

(g) Awarding such further relief as is proper.

JURY TRIAL IS DEMANDED

Dated: New York, New York
March 13, 2018

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